

REMARKS

With the cancellation of the allowed claims 11-17, 20-29, 32-34, 36, 41-44 and 47-51, and the cancellation of the objected claim 30, claims 1-3, 5-10, 18, 19, 31, 35, 37-40, 45 and 46 are pending.

The amendment to claim 19 is editorial and would not narrow the scope of the amended claim recitation.

Claims Allowed

Applicants would like to thank Examiner Berch for allowing claims 11-17, 20-29, 32-34, 36, 41, 42, 44 and 47-51. But these allowed claims have been canceled and will be presented in a divisional application.

Claim Objection

Claim 30 was objected to as dependent on a rejected base claim, but was held to contain allowable subject matter. But claim 30 has been canceled and will be presented in a divisional application. Withdrawal of the objection is requested.

Claim Rejection -- 35 U.S.C. 112, Second Paragraph

Applicants respectfully traverse the indefiniteness rejection of claim 5. Claim 5 differs from claim 1 in that “another famciclovir crystalline form” in claim 1 can mean form II, the methanol solvate, the ethanol solvate or the monohydrate. In contrast, it means “form II” in claim 5.

Claim Rejections -- 35 U.S.C. 112, First Paragraph

Applicants respectfully traverse the rejections of claims 45 and 46 for failing to comply with the written description requirement. The original claim 41 as filed recites “wherein the crystalline solid famciclovir form III contains less than about 5% wt of other famciclovir crystalline forms.” Page 7, lines 19-20, of the specification discloses that form III can be a methanol solvate or an ethanol solvate. As a result, applicants submit that there is written descriptive support for claims 45 and 46.

Applicants also respectfully traverse the non-enablement rejection of claim 35. The Examiner took a position that Brand did not produce famciclovir monohydrate when recrystallizing from aqueous acetone, and the Examiner concluded that the method of claim 35 for preparing famciclovir monohydrate is not enabled. However, Brand did not provide details

on how the famciclovir was crystallized from aqueous acetone. Brand also did not provide details on the procedure used to do the elemental analysis. Claim 35 recites the use of water mixed with ethanol, DMF, DMA, acetonitrile, methanol, THF or isopropanol, which was demonstrated by Example 10 to succeed in making famciclovir monohydrate. Applicants contend that, regardless the disclosures of Brand, it would not be undue experimentation for one skilled in the art to prepare famciclovir monohydrate according to the process of claim 35.

Withdrawal of the rejections under 35 U.S.C. 112 is requested.

Claim Rejections -- 35 U.S.C. §102

(A) Applicants respectfully traverse the anticipatory rejection of claim 35 over Harnden 1990 (*Nucleosides & Nucleotides* (1990) 9:499-513). Harnden 1989 discloses a process of preparing famciclovir requiring two steps of solvent removal. Thus, even if one were to assume for argument purposes only that the twice extraction with chloroform may carry several molecules of residual methanol, the residual methanol would have been removed.

The Examiner also argued that famciclovir can form a methanol solvate. But there would have been no methanol remaining because of the first solvent removal step in Harnden 1989. Even if, for argument purposes only, one were to assume that there were several molecules of residual methanol remaining, the formation of the famciclovir methanol solvate would keep the methanol molecules inside crystalline famciclovir methanol solvate so that there would be no methanol/water mixture.

Withdrawal of the anticipatory rejection is requested.

(B) Applicants also respectfully traverse the anticipatory rejections of claims 1-3, 5-10, 18, 19, 31, 37-40 and 43 over Harnden 1989 (*J. Med. Chem.* (1989) 32: 1738-1743); US 5,017,701; US 5,066,805; US 5,138,057; US 6,846,927; US 6,342,603; Freer (*Tetrahedron* (2000) 56:4589-4595); US 6,437,125 and WO 2000/06573.

The Examiner took a position that the crystalline forms of the claims are merely properties of famciclovir, and as a result this “is not an ordinary inherency situation where it is explicitly stated what the product actually is.” Applicants respectfully disagree. The phenomenon that famciclovir can form a number of crystalline forms is a property of famciclovir. But applicants contend that the specific crystalline forms now claimed are not properties of famciclovir as physical properties such as melting point or boiling point. If the prior art discloses a compound and if a hypothetical applicant claims the compound as having a property, such as the melting point, not explicitly disclosed in the prior art. Then the hypothetical applicant has the burden to prove that the prior art compound does not have the inherent property recited in the claims. However, the situation is different here. When any of

the cited prior art references discloses a solid form of famciclovir, it does not necessarily flow from the disclosures in the prior art that the solid form of famciclovir of the prior art is the specific crystalline form claimed. There is no evidence that the specific crystalline form claimed would necessarily be formed according to the processes disclosed in the prior art in order to allow proper anticipatory rejections of the claims under the inherency principle.

Withdrawal of all the anticipatory rejections is requested. Even though the applicants disagree with the anticipatory rejections, to advance prosecution the applicants would be willing to consider experimental showing if the claims are otherwise indicated to be allowable.

Conclusion

With the above reasoning, applicants submit that the application is in a condition for allowance. The Examiner is urged to contact the undersigned by phone if there remains any minor issues.

In the event that the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The petition fee and any other fees that may be required in relation to this paper can be charged to Deposit Account No. 11-0600 referencing Attorney Docket No. 01662/60903.

Respectfully submitted,

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